

Regulation of Risk and Innovation

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Innovation and Growth

- Innovation is the long-term driver of economic growth
- Flourishes when societies create conditions in which investors, managers, and entrepreneurs are encouraged to take risks
- Includes creation and introduction of new products and services and the use of new processes and operating methods. It includes revolutionary changes and changes resulting from continuous improvement. It is important for companies of all types in all sectors
- Companies play the leading role – MNEs continue to be of central importance
- Governments have a major role to play in creating a business environment that is supportive of innovation

Business Environment for Innovation

- Stable and supportive macro-economic framework
- Enabling Conditions
 - *Positive attitudes towards risk, enterprise, and new technologies*
 - *Favourable market conditions*
 - *Broad development and widespread dissemination of new knowledge and ideas*
 - *Ready availability of well-qualified people*
 - *Easy access to capital*
- Traditionally government support focuses on R&D, national innovation systems
- Regulation of risk affects important aspects of the business environment

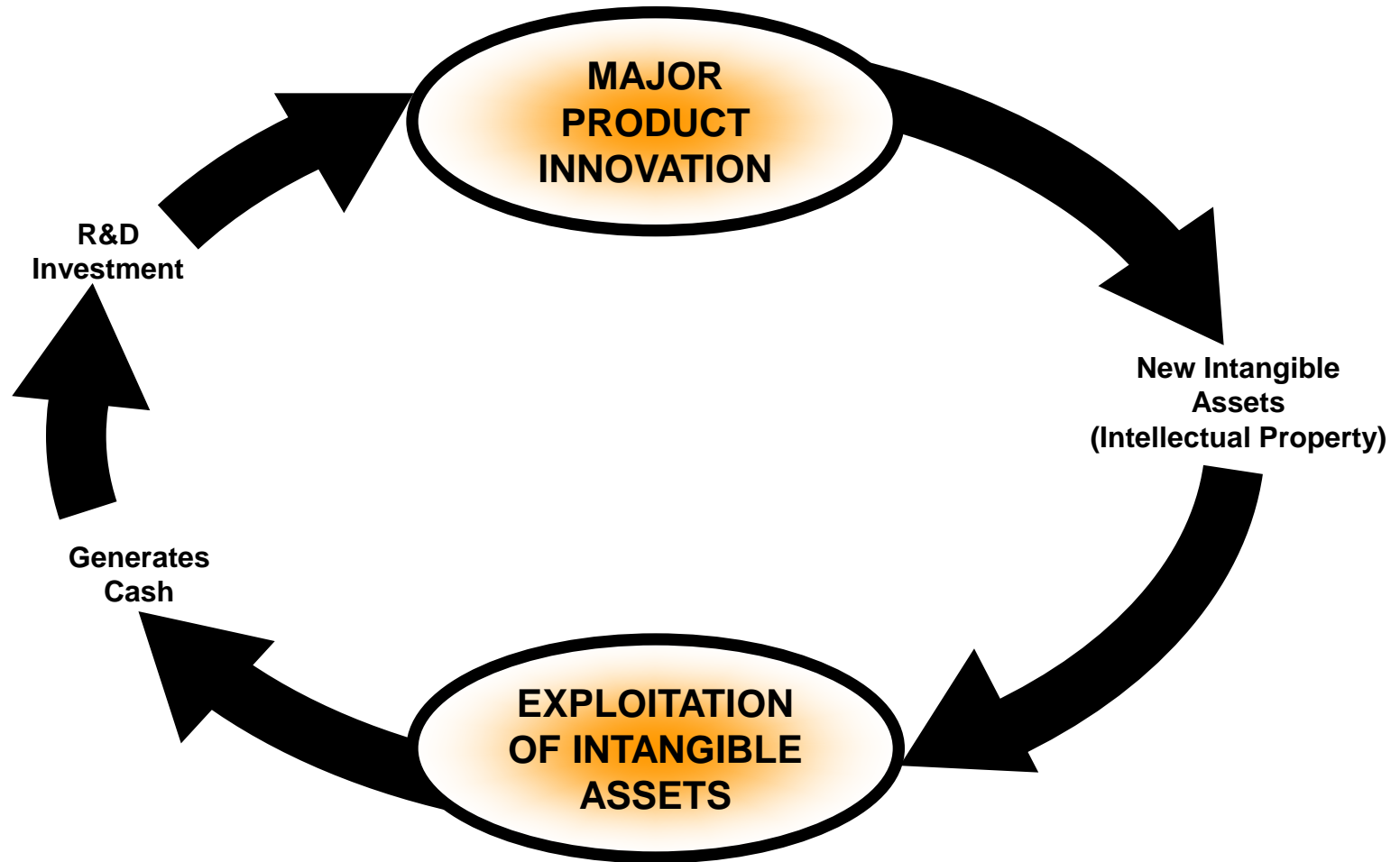
Attitudes to New Technologies and Ideas

- Attitudes influence risk-taking, regulatory framework, acceptance of new products, market opportunities, development of new operating processes
- Risk management issues:
 - *Positive role in creating market opportunities - user confidence and public trust in science and technology*
 - *Legislative and political policies – risk acceptance or risk aversion*
 - *Dissemination of new technologies – stigmatisation or neutrality*
 - *Basis for risk management – use and extent of precaution*
 - *Technical decision-making and existing platform technologies – hazard and stigmatisation or risk and evidence-based approach*
 - *Regulatory process management – understanding complex regulatory impacts, oversight of technical decision-making procedures*

Market Conditions

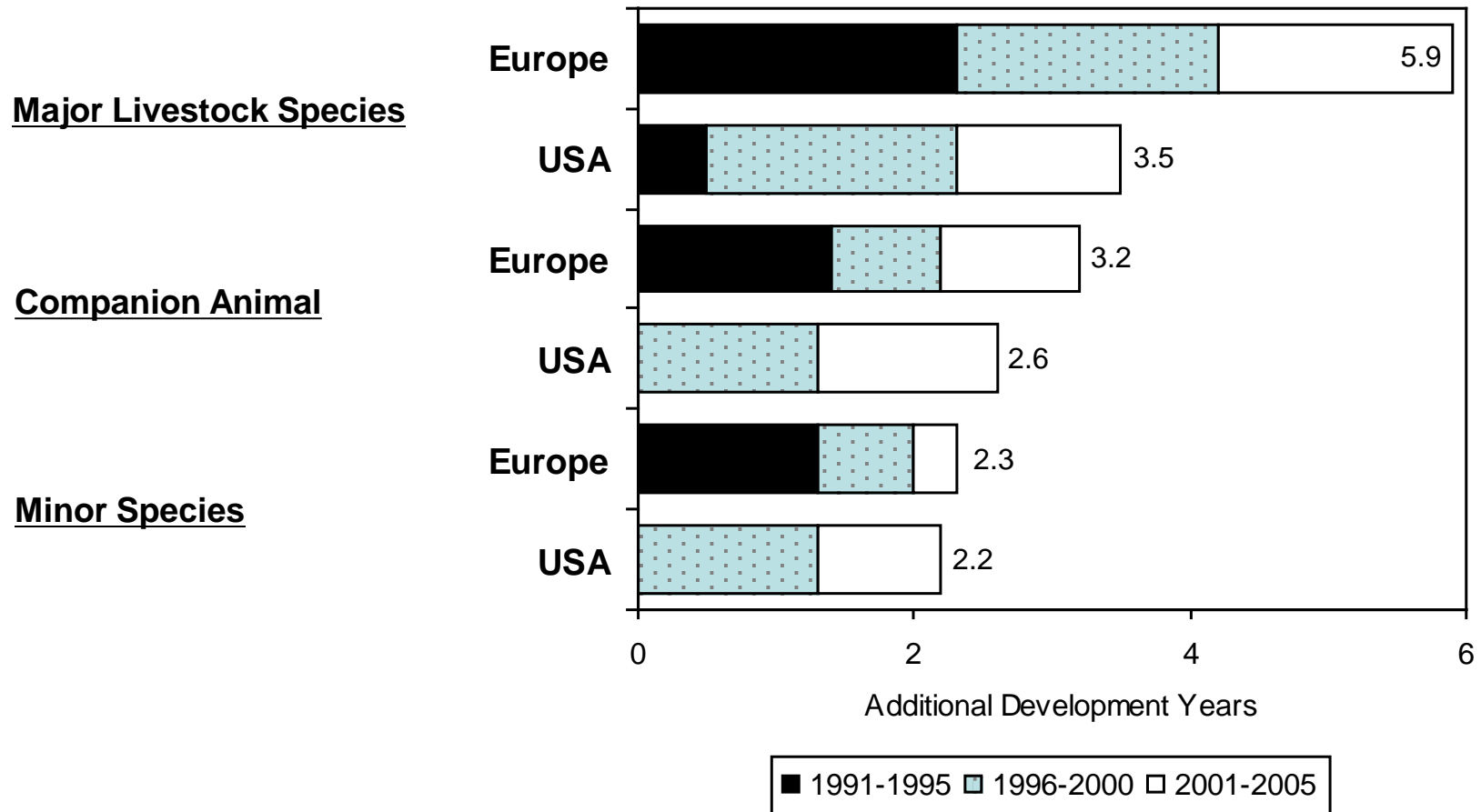
- Release of market potential depends upon demand factors (early adopters, scale of demand), infrastructure, and innovation economics
- Risk management decisions can play a major role in shaping product development decisions by private sector because affect effective scale of market and expected cost of innovation
- Risk management issues:
 - *Positive role – ensure safety standards, develop intangible assets, create level playing field, single market, create user confidence, reduce investment risk (predictable, proportionate approval processes)*
 - *Legislative and political strategies – social acceptance of risk, pre-market approval requirements and processes, bases for risk management decisions (hazard and other factors or science and risk)*
 - *Nature and role of guidelines in technical decision-making – time and cost of product development*
 - *Type of technical decision-making process – opacity, administrative discretion and politicisation or transparency, science-based, and predictability*
 - *Regulatory process management – understanding impacts of agencies, guidelines, and rule-making, applying decision-making rules to technical decisions, understanding of economics of product development decisions and complex regulatory impacts*

The “Innovation Cycle” in the Animal Health Industry



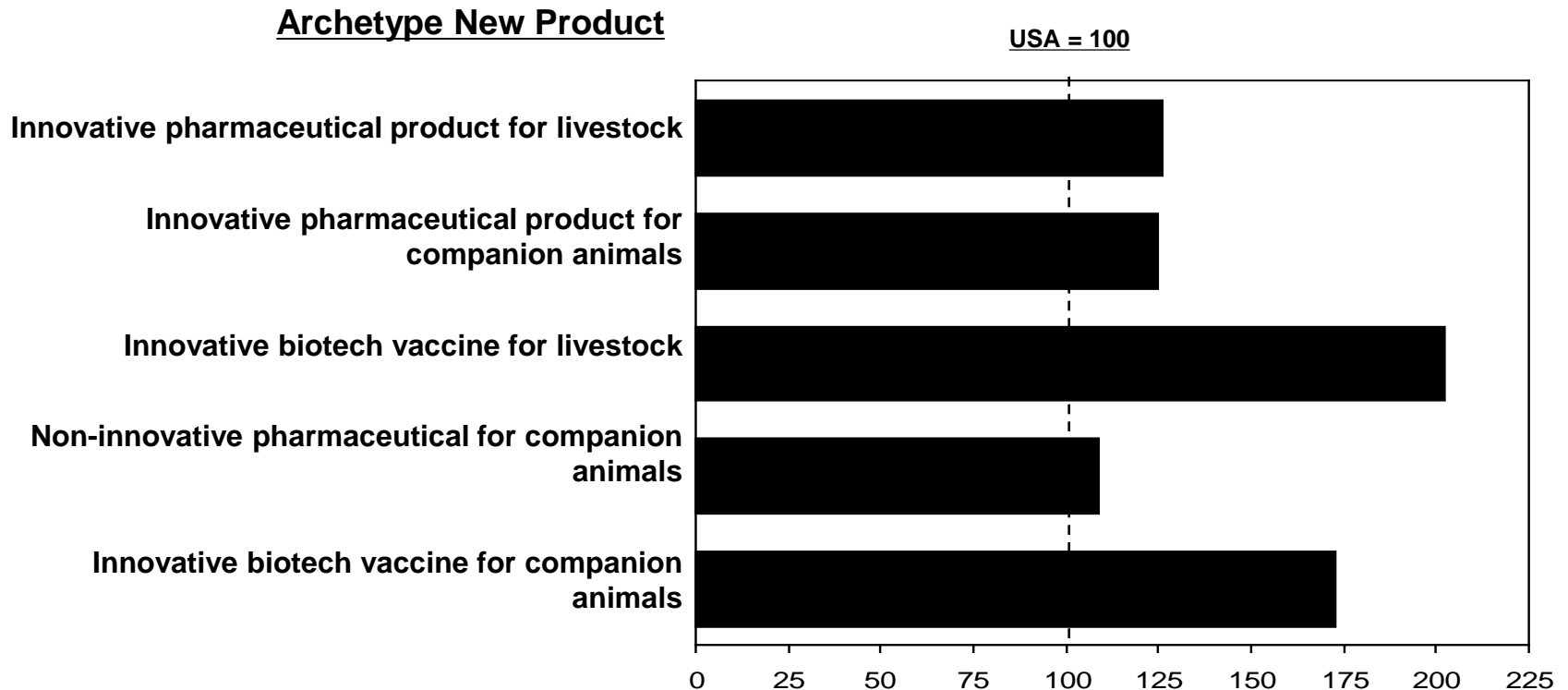
Impact of Regulatory Factors on the Average Length of Time Taken to Develop a New Product in Europe and the USA

(changes over the fifteen year period 1991-2005)



Expected Total Capitalised Cost Needed to Develop and Achieve Regulatory Approval for Archetype New Products

Europe compared to the USA (where USA = 100)

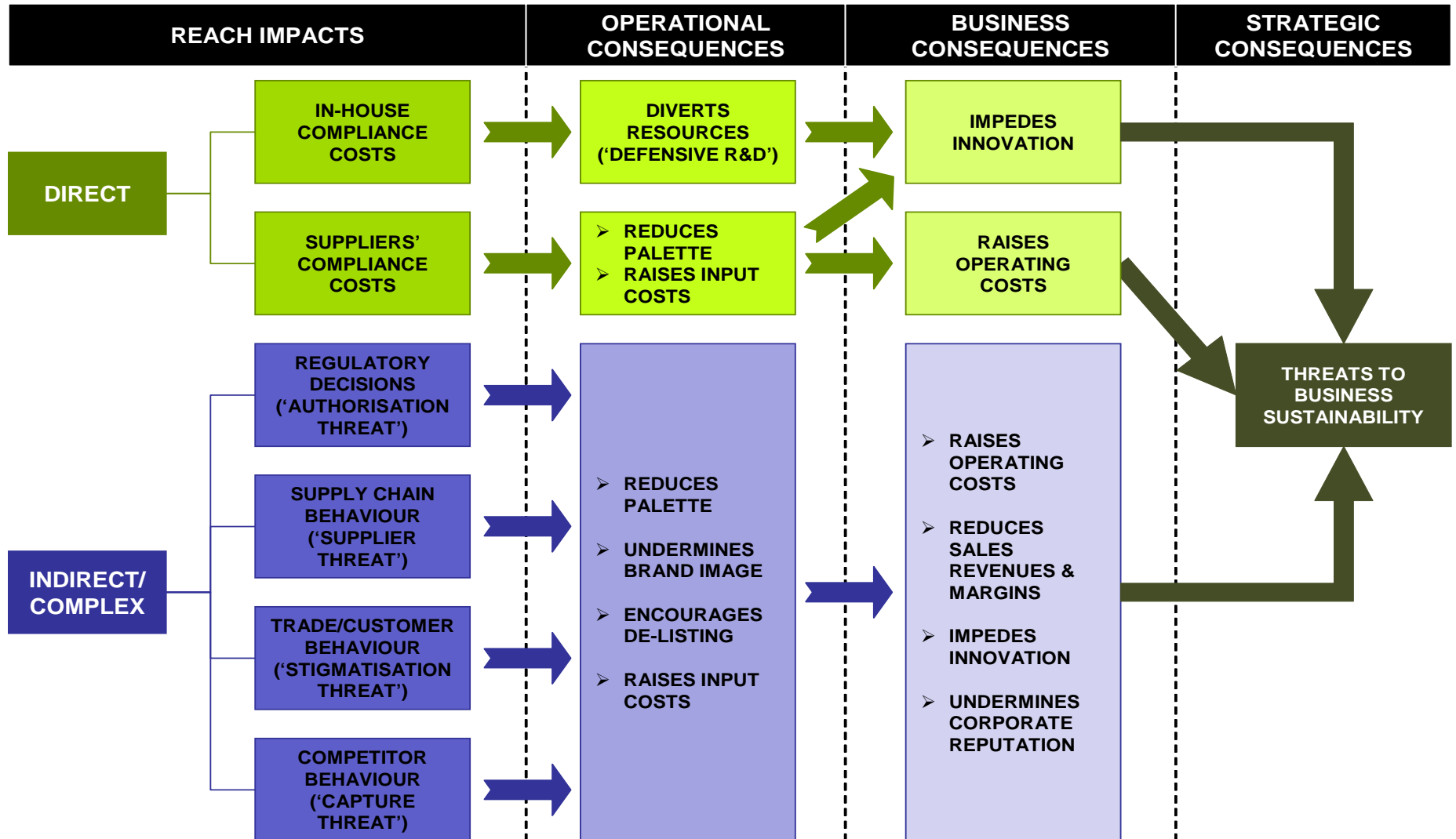


*Note: Includes capitalised cost required for development, scientific assessment and marketing approval

Creation and Diffusion of Ideas

- In modern economies, many innovators depend on embedded technologies – many of these are well-established substances and materials
- Risk management decisions can affect the availability and attractiveness of well-established platform technologies, limiting the diffusion of ideas.
- Risk management issues:
 - *Positive role – sustain access to ideas, build confidence in established technologies*
 - *Legislative policies – objectives (risk reduction or “better world”), social acceptance of risk, role of hazard-based decisions, design and quality of risk management laws*
 - *Technical regulatory decision-making – costs and benefits of stigmatisation, scientific evidential standards and peer review, role and basis of listing decisions*
 - *Regulatory process management – understanding of stigmatisation and defensive R&D processes, awareness of risk-risk trade-offs, importance of ex post evaluation*

REACH IMPACT MAP



Recommendations

- Adopt an “Innovation Principle” – applies to all new laws and rules
- Establish a formal regulatory policy to support innovation – science-based risk assessment and management; balance proportionality and precaution; relevant expertise
- Amend impact assessment processes to require formal evaluation of impacts on innovation
- Develop IA guidelines to support evaluation of complex costs and benefits, including adoption of new technologies, demand stigmatisation, product development economics, Defensive R&D
- Introduce formal regulatory standards for the use of science in legislative and regulatory decision-making
- Require ex post evaluation of effectiveness and impacts of risk management laws and rules, ensuring amendment or reversal where new evidence becomes available
- Establish institutional structures, close to the centre of political decision-making, with responsibility for reviewing the use of scientific evidence in risk management